

## REMARKS

Claims 1-41 are currently before the examiner. Claims 7-12, 16-18, 28-33 and 37-39 have been withdrawn by the examiner as, in the examiner's opinion, relating to a separate and distinct invention. Claims 1-6, 13-15, 19-27, 34-36, 40 and 41 stand rejected.

### **35 U.S.C. § 103 rejection of claims 1, 3-6, 13-15, 19-21, 23-27, 34-36, 40 and 41**

The examiner has rejected claims 1-6, 13-15, 19-24, 26, 27, 34, 40, and 41 as being unpatentable over Katsarava, et al., U.S. Pub. Pat. App. No. 2002/0015720 in view of Katsarava, et al., Journal of Polymer Science: Part A, 1999, 37:391-407 (Katsarava B), Nagata, Polymer International, 1997, 42:33-38; and Bezemer, et al., Journal of Biomedical Material Research, 2000, 52:8-17.

The examiner in essence repeats the previous rejection of the instant application over Katsarava in view of Katsarava B and Nagata. Then, in the Response to Arguments, the examiner states that "Applicant's arguments, filed June 30, 2009, have been fully considered but they are not deemed to be persuasive. Nevertheless an additional reference is cited to add support to the previous rejection over Katsavara et al. in view of Kasavara, et al. reference B and Nagata." The additional reference is Bezemer, which the examiner apparently offers for the proposition that block copolymers comprising poly(ester amides) blocks and poly(ether ester amide blocks) were known and therefore it would have been obvious to judiciously select monomers from the Katsavara references in view of Nagata and combine them as set forth in Bezemer to arrive at the polymers of the instant invention.

Applicant traverses.

### **Applicant's response**

Applicant previously presented the following argument (paraphrased) in contravention of obviousness of the current invention over Katsavara in view of Katsavara B and Nagata:

Nowhere in Katsarava, Katsarava B or Nagata and/or are copolymers disclosed. Applicant's polymers are all copolymers. Nagata teaches only polyesters while the current invention is directed solely to poly(ester amide)s, a entirely different class of compounds. Nevertheless, the examiner argues that one of ordinary skill in the art would be

motivated based on Katsarava and Katsarava B to make CADA-CADA copolymers (Katsavar's short hand designation). To do so the skilled artisan would have had to decide, based on Nagata's work with an entirely different type of polymer, to substitute Nagata's poly(ethylene glycol) for one and only one of the hexanediol elements (the D's) of the CADA-CADA copolymer.

Applicant pointed out that there was nothing in any of the references to teach, suggest or motivate the person of average skill in the art to consider making a copolymer. Katsarava and Katsarava B are explicitly limited to CADA and DACA polymers and Nagata to polyesters; neither discloses block copolymers

In the current rejection, the examiner invokes Bezemer to attempt to overcome the element missing in Katsavara, Katsavara B and Nagata: the linking together of two of Katsavara's CADA units and then replacing one of the hexanediol D's with poly(ethylene glycol) to arrive at the copolymers of the instant invention. The examiner opines that the two blocks of applicant's polymers would have been obvious over Katsavara and Katsavara B by invoking Nagata for the proposition that integration of PEG into the poly(ester amide) to confer "additional avenue of enzymatic degradation *in vivo*" would have been seen as valuable by a skilled artisan and, therefore, it would have been obvious to that artisan to construct a biopolymer (copolymer with two and only two distinct blocks) with one PEG unit and one hexanediol unit based on Bezemer which, in the examiner's view, teaches such copolymers. An additional extension the examiner notes would have to be considered by the skilled artisan is the selection of "8-L-leu-6" polymer taught by Katsavara B as the base poly(ester amide). Then the examiner expounds on the amount of dicarboxylic acid that would be necessary so that there would be one dicarboxylic acid moiety for each monomer unit to arrive at the instant polymers.

While nicely rationalized, the examiner's argument fails. Applicants iterates the argument that Katsavara, Katsavara B and Nagata fail utterly to teach, suggest or motivate the skilled artisan to make a CAD<sub>1</sub>A-CAD<sub>2</sub>A copolymer. Bezemer does nothing to cure this fatal defect. That is, Bezemer teaches multi-block copolymers having the structure, using Katsavara's letter designation for the monomers as far as they pertain:

...(CMCD<sub>1 or 2</sub>)-(CMCD<sub>1 or 2</sub>)... where M designates a diamine, an element not present in Katsavara. That is, Bezemer first makes a diester-diamide from a diester and diamine with unreacted ester groups at either end of the prepolymer and then performs a transesterification to exchange PEG and hexane diol for the simple ester group on the diesters. No  $\alpha$ -aminoacids, a central component of the Katsavara references, are involved at all. Further, the present invention, as noted above, comprises a bipolymer, a block copolymer having two and only two distinct blocks whereas the number of blocks in Bezemer is limited only by the amount of  $\alpha,\omega$ -diols (the PEG and hexane diol). Thus, the combination of Katsavara, Katsavara B, Nagata and Bezemer does not and cannot render the present invention obvious.

The examiner is requested to reconsider and based thereon withdraw the rejection.

### **35 U.S.C. § 103 rejection of claims 1, 2, 21 and 22**

The examiner has rejected claims 1, 2, 21 and 22 under § 103(a) as being unpatentable over Katsarava, Katsarava B in view of Nagata and, further, in view of Michal, U.S. Pub. Pat. App. No. 2002/01120326.

In the examiner's view, Katsarava, Katsarava B and Nagata render obvious a coated medical article and its claimed method of production where the polymer coating includes applicant's poly(ester amide)s. The examiner, however, admits that none of the preceding references explicitly teach that the article is a stent but Michal does.

Applicant traverses.

### **Applicant's response**

As explicated at length above, Katsarava, Katsarava B and Nagata, with or without Bezemer, do not render obvious a coated medical article and its claimed method of production where the polymer coating includes applicant's novel copolymeric poly(ester amide)s. All that Michal teaches that might be significant if Katsavara, Katsavara B and Nagata in fact rendered applicant's polymers obvious, which they do not, as the examiner notes, that poly(ester amide)s can be used on stents. Like Katsarava, Katsarava B and Nagata, however, Michal makes no mention of copolymeric poly(ester amide)s and therefore cannot even arguably supply the missing element in Katsarava, Katsarava B and Nagata. The combination of Katsarava,

Katasarava B, Nagata and Michal cannot and does not render claims 1, 2, 21 and/or 22 obvious.

The examiner is requested to reconsider and based thereon withdraw the rejection.

### **CONCLUSION**

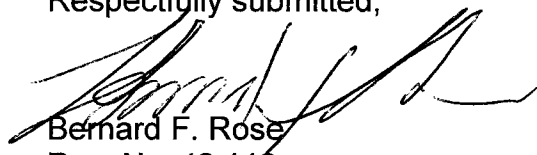
Based on the above remarks, applicant believes that this application is in condition for allowance and respectfully requests that it be passed to issue.

Applicant does not believe any fee is due with this response. If this is incorrect, the examiner is authorized to charge any amount due to Squire, Sanders & Dempsey Deposit Account No. 07-1850.

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Respectfully submitted,



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